

IX. PROCEDURES FOR COLLECTING SALIVA

As has been discussed in previous chapters, the Pregnancy Advisor Assistant is responsible for collecting saliva from all participating women who finalize an evaluation interview. The purpose of the saliva collection is ultimately to analyze the specimen for the presence of cotinine, which is a marker for exposure to tobacco smoke. Thus, when you collect the saliva from a participant, you will also administer a brief questionnaire that asks questions about recent exposure to tobacco smoke. The specimen is then sent to a laboratory for analysis.

A. Materials

Once you have identified a woman as needing saliva collection, you must prepare all of the necessary materials. You will need to assemble the following materials for each participant who requires saliva collection on a given day:

1. Plastic Gloves.
2. Saliva Collection Device. This contains the following four components, which fit inside one another:



a. Stopper



b. Cotton wool swab



c. Suspended Insert



d. Centrifuge vessel

3. Saliva Test Requisition Form. You must complete this form for every specimen that you collect. You will record information about the participant and the saliva collection, including the Subject ID, date of collection, clinic site, and type of evaluation (baseline, second trimester follow up, third trimester follow up, postpartum). A sample Saliva Test Requisition Form is provided as Exhibit IX-1.
4. Specimen Bag. This bag has two pockets, one for the saliva collection device and the second for the requisition form. Each specimen will have its own bag.

5. Tobacco Smoke Exposure Questionnaire. As shown in Exhibit IX-2, this is a brief questionnaire that asks several questions about the woman's recent exposure to tobacco smoke. You will need to attach the woman's Subject ID label to the form and record the date of saliva collection on it.
6. Identification Labels (3). As discussed in Chapter XI, you will use the Data Management System to generate identification labels for each participant. These labels will include the participant's Subject ID, as well as a bar code. You will need to affix an identification label to the outside of the saliva collection device for each participant who provides the sample, to the Saliva Test Requisition Form, and to the Tobacco Smoke Exposure Questionnaire.

B. Collecting the Saliva

After you have identified a woman as requiring saliva collection, you should approach her for the collection. The location and timing of your approach will vary from clinic to clinic, and site-specific instructions are provided in Appendix A. Make sure that you have all of your materials ready, including your Daily Log to record the activity completion, as well as the saliva collection device, Saliva Test Requisition Form, and the Tobacco Smoke Exposure Questionnaire.

1. Specimen Collection

The specimen collection is an easy, noninvasive procedure. You should follow these instructions in obtaining the sample. Note that the parts of the saliva collection device described in these instructions are pictured above.

- a. Put on a clean pair of plastic gloves.
- b. Hold the saliva collection device at the rim of the suspended insert (c) and remove the stopper (a). Removal of the stopper is easier if you slightly push it to the side when opening the suspended insert. The suspended insert will remain inside of the centrifuge vessel (d).
- c. Give the device to the participant and ask her to remove the cotton wool swab (b) from it.
- d. Instruct the participant to chew on the cotton wool insert. She should keep the cotton in her mouth until she feels that she can no longer prevent herself from swallowing the saliva she is producing. This normally takes about 30 to 45 seconds, although it may take a little bit longer.
- e. At this time, the participant should return the cotton wool swab (b) to the suspended insert (c) and return the saliva collection device to you.

- f. Close the saliva collection device firmly with the stopper (a).
- g. Write today's date (the date of collection) on the participant's identification label and ensure that the label is affixed to the saliva collection device.
- h. Place the saliva collection device in the back pouch of the specimen bag. The Saliva Test Requisition Form will go in the front pocket.
- i. When both the saliva collection device and the Saliva Test Requisition Form are in the bag, remove the tape liner and fold the bag at the score to close and seal it.

2. Saliva Test Requisition Form

While the participant is preparing the sample, you should fill out the Saliva Test Requisition Form. Note that filling out the form can be tricky, as much of the information that you will record is somewhat different than the information requested on the form. The instructions below describe exactly what information to record in every field of the form. Please follow these instructions carefully:

- *Collection date*: Write the date on which you are collecting the saliva specimen.
- *Collection time*: Indicate the **type** of interview for which you are collecting the saliva, either baseline (BL), first prenatal follow up (FU1), second prenatal follow up (FU2), or postpartum (PP). Note that this information is provided for all participants in the Saliva Collection Report. It can also be obtained from an Individual Activity Summary. (Note that the first prenatal follow up occurs at 22-26 weeks of gestation, and the second prenatal follow up occurs at 34-38 weeks of gestation).
- *Referring Physician*: Fill in your **clinic site** here.
- *Patient Name*: Leave this field blank. **Do not fill in the participant's name.**
- *Birth date*: Record the participant's date of birth. Note that this information is provided for all participants in the Saliva Collection Report. It can also be obtained from an Individual Activity Summary.
- *Sex*: All participants are female.
- *Patient's Social Security Number*: Affix the participant's **Subject ID label** to the space in this field. Do not ask the participant for her social security number.
- *Other Information*: Leave this field blank.
- *Indicate test*: Check the **middle box**, which reads:

[] **COTININE, SALIVA: GC/MS TEST (sensitive 10 ng/ml)**

INSERT SALIVA TEST REQUISITION FORM

When you have filled out the Saliva Test Requisition Form as described above, place it in the front pocket of the specimen bag (the saliva collection device goes in the back pouch). Dispose of your plastic gloves in the appropriate receptacle.

C. Tobacco Smoke Exposure Questionnaire

After you have collected the saliva sample, you should immediately administer the Tobacco Smoke Exposure Questionnaire. Before you begin, affix the subject's identification label to the questionnaire and fill in the date and site of the saliva collection. The questionnaire is brief and will take only a few minutes to complete. A copy of the questionnaire is provided in Exhibit IX-2.

Remember that a professional interviewer helps each woman feel at ease and comfortable with the interview. One key to accomplishing this goal is to be fully informed about the data collection instrument and procedures. Thus, before you begin interviewing, you should be familiar with the conventions of questionnaire design and with the content of this questionnaire.

1. Standardization of Questionnaire Administration

Standardization of interview administration means that, to every extent possible, every interviewer is administering every questionnaire to every woman in the same way. This helps to eliminate variability and interviewer bias, two factors that can seriously affect the validity, or "believability," of the data. The manner in which you as the interviewer ask the questions can vary, and it is this variability that must be minimized.

Following the guidelines listed below will help to ensure that you are administering the questionnaire in an unbiased, standardized manner.

- Always maintain a neutral attitude. Be careful that nothing in words or manner implies criticism, surprise, approval, or disapproval of the question or response.
- Ask the questions using the exact words printed in the questionnaire. Altering the wording of the question or reordering words or phrases within a question may affect the woman's answer.
- Stress words that are underlined. Do not read answer choices or interviewer instructions that are printed in ALL CAPS.
- Ask the questions in the exact sequence in which they appear in the questionnaire, unless you are instructed otherwise. An answer to one question may influence an answer to another. The meaning of a question may change or be unclear if it is asked out of sequence.

INSERT TOBACCO SMOKE EXPOSURE QUESTIONNAIRE

- Ask every question specified in the questionnaire. Do not assume that the answer to an upcoming question has already been provided, because the answer received in the context of one question may not be the same answer that will be received when the question is asked directly.
- Repeat questions that are misinterpreted or misunderstood by the woman.
- Avoid suggesting answers to the woman. When providing answer choices, always read all of the choices listed.
- Use transition statements as they are printed on the questionnaire. Since there are several topics covered in the questionnaire, transitional statements will help the woman focus on a new topic as it occurs in the sequence of the questionnaire.
- Read the complete question, as printed. The woman may interrupt you and answer before having heard the complete question. When this happens, read the question again, making sure she hears it through to the end.
- Read the questions slowly. As you become more and more familiar with the questionnaire, you may be tempted to read through the questions more quickly, perhaps in an effort to reduce the burden for the respondent in terms of the time spent doing the interview. However, you must remember that this is the first time she has heard these questions, and therefore you must read slowly enough so that she can understand everything you are asking. A pace of about 1 or 2 words per second is considered to be desirable.
- Record all responses immediately. Start writing as soon as the woman starts talking. If you miss part of a response, repeat what the woman has said up to that point, and then pause expectantly. Let the woman supply the remaining response.
- Record the response verbatim. Record the actual words spoken by the woman. Paraphrasing or summarizing may result in a distortion of the real response.
- Record legibly and in pencil.
- Do not leave an applicable question blank. If a woman does not answer a question, note the reason for the lack of response, either “refused” or “don’t know,” in the left-hand margin, next to the question.

2. Question Specifications

Most of the questions in the Tobacco Smoke Exposure Questionnaire do not require additional clarification, and they include directions for you to follow, such as skip instructions and reading and recording instructions. However, several questions do require clarification and instruction, as follows:

- Q.1** The woman may answer this question in terms of hours, days, weeks, months, or years, whichever is easiest for her. If she indicates that she has never smoked, you will circle code –7 and then skip to Q.4. If she indicates that it has been longer than 7 days (one week) since she smoked, regardless of how (in what terms) she expresses the answer, you should fill in the appropriate response and also skip to Q.4.
- Q.5** If the woman hesitates in answering this question, you should help her come up with the answer by going through the question mathematically. You will ask how many people smoked in her home in the past 7 days, and how many cigarettes each of these people smoked.

D. Preparing the Saliva for Shipment to the Laboratory

Once you have obtained the saliva sample and administered the questionnaire, check column **D-2** on your Daily Log, indicating that the participant has completed the saliva collection. You must then prepare the specimen for shipment to the laboratory. *The specimens must be mailed on the same day that they are collected.* Note that the Tobacco Smoke Exposure Questionnaire is not sent to the laboratory. Questionnaires for all participants should be filed together in your filing cabinet (not in the participant's folder). All completed Questionnaires will be sent to RTI for data entry on a weekly basis.

To prepare the saliva specimen for shipment, as described above, you should have placed the saliva collection device and completed Saliva Test Requisition Form in the specimen bag. Make sure that you have sealed the bag, and then place the specimen in the mailing box. You will have a supply of pre-folded, pre-addressed, and pre-stamped boxes in which to mail the specimens. Note that you may put up to 8 specimens in one shipping box.

At the end of every day, you should seal the box containing all of your specimens and put it in the mailbox to go to J2 Laboratories. You will need to consult the clinic liaison to obtain information on how boxes may be mailed via the U.S. Postal System from the clinic for same-day pickup.